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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,267	10/31/2001	Lakshmi Rambhatla	093/004P	1874
22869	7590	10/03/2003	EXAMINER	
GERON CORPORATION 230 CONSTITUTION DRIVE MENLO PARK, CA 94025			TON, THAIJAN N	
			ART UNIT	PAPER NUMBER
			1632	

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/001,267		RAMBHATLA ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Thái-An N. Ton		1632	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

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|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.  |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other:  |

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-5 and 9, drawn to cell populations, classified in class 435, subclass 325, 363, for example.
- II. Claims 6 and 7, drawn to methods for obtaining the cell populations, comprising culturing cells from the stem cell line in a growth environment that comprises a hepatocyte differentiation agent which is histone deacetylase inhibitor, classified in class 435, subclass 325, 363, 377, for example.
- III. Claim 8, drawn to methods for obtaining the cell population, comprising culturing cells from the stem cell line in a growth environment that comprises one or more hepatocyte maturation factors, classified in class 435, subclass 325, 363, 377, for example.
- IV. Claim 10, drawn to a method of screening a compound for hepatocellular toxicity, classified in class 435, subclass 4.
- V. Claims 11 and 12, drawn to a method of screening a compound for its ability to modulate hepatocellular function, classified in class 435, subclass 4.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and either of Inventions II or III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the cell populations of Invention I can be isolated from tissue or organ sources.

Inventions I and either of Inventions IV or V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the cell populations of Invention I can be used in cellular transplantation therapies.

Inventions II and any of Inventions III-V are mutually exclusive and independent inventions. The method for obtaining the cell populations, comprising culturing cells from the stem cell line in a growth environment that comprises a hepatocyte differentiation agent which is histone deacetylase inhibitor of Invention II is not required for the implementation of the methods for obtaining the cell population, comprising culturing cells from the stem cell line in a growth environment that comprises one or more hepatocyte maturation factors of Invention III, the method of screening a compound for hepatocellular toxicity of Invention IV, and the method of screening a compound for its ability to modulate hepatocellular function of Invention V, and vice versa. Furthermore, each of the methods requires a materially different and separate protocol.

Inventions III and either of Inventions IV or V are mutually exclusive and independent inventions. The methods for obtaining the cell population, comprising culturing cells from the stem cell line in a growth environment that comprises one

or more hepatocyte maturation factors of Invention III are not required for the implementation of the method of screening a compound for hepatocellular toxicity of Invention IV, and the method of screening a compound for its ability to modulate hepatocellular function of Invention V, and vice versa. Furthermore, each of the methods requires a materially different and separate protocol.

Inventions IV and V are mutually exclusive and independent inventions. The method of screening a compound for hepatocellular toxicity of Invention IV is not required for the implementation of the method of screening a compound for its ability to modulate hepatocellular function of Invention V, and vice versa. Furthermore, each of the methods requires a materially different and separate protocol.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one

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claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thái-An N. Ton whose telephone number is (703) 305-1019. The examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time), with alternating Fridays off. Should the examiner be unavailable, inquiries should be directed to Deborah Reynolds, Supervisory Primary Examiner of Art Unit 1632, at (703) 305-4051. Any administrative or procedural questions should be directed to William Phillips, Patent Analyst, at (703) 305-3482. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703)-872-9306.

TNT

Thái-An N. Ton  
Patent Examiner  
Group 1632

*Jai Waitail*  
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